EXHIBIT I

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	**A. Prosser**	ALJ Appeal No.:	**1-8416188648**
Beneficiary:	**A. Prosser**	Medicare Part:	**B**
DOS:	**8/16/2018** **9/16/2018** **10/16/2018**		
HICN:	*******9206A**	Before:	**Kimberley Woodyard** U.S. Administrative Law Judge

DECISION

Upon a *de novo* review of the record, this Administrative Law Judge enters a **FULLY FAVORABLE** decision for the Appellant, Anniken Prosser. Ms. Prosser is entitled to coverage for Tumor Treatment Field Therapy (E0766).

FINDINGS OF FACT AND HISTORY OF THE CASE

Ms. Prosser, was thirty-four years old at the time of services. (Exh. 2, p. 1). On February 14, 2016, MRI results showed Ms. Prosser had a large left cystic temporal mass. *Id.* Two weeks later, she underwent a left craniotomy. *Id.* The post-operative diagnosis was "GBM" (glioblastoma multiforme). *Id.*

In May 2016, Ms. Prosser completed radiation with Editha Kruegar, MD, and concurrent Temodar chemotherapy with Jasleen Randhawa, MD. (Exh. 2, p. 1). In June 2016, adjuvant Temodar chemotherapy was continued, and Optune TTFields therapy was started. *Id.* By April 2017, she had completed twelve cycles of Temodar chemotherapy, and Optune TTFields therapy was continued. *Id.*

On March 15, 2018, Jennifer Connelly, MD, examined Ms. Prosser. (Exh. 2, pp. 1-4). Dr. Connelly found Ms. Prosser was neurologically intact and radiographically stable, and she was tolerating TTFields well with excellent compliance. (Exh. 2, p. 4). Brain imaging showed similar

results compared to the previous images. *Id.* There were no new lesions, and no evidence of abnormal vascularity. *Id.* Dr. Connelly recommended continuing with Optune TTFields. *Id.*

On June 2016, Ms. Prosser began using Optune therapy treatment. (Exh. 5, p. 1,649). On April 13, 2018, and on October 11, 2018, Dr. Connelly signed an Optune Prescription Form renewing the Optune treatment prescription for an additional six months. (Exh. 5, pp. 1,650-1,651). The record includes invoices for Optune for August 16, 2018, September 16, 2018, and October 16, 2018. (Exh. 2, pp. 1,645-1,647).

Optune Background

When Optune is turned on, it creates low-intensity, wave-like electric fields call Tumor Treating Fields, or TTFields. (*See* https://www.optune.com/discover-optune/how-optune-works). These TTFields are delivered by transducer arrays to the location of a GBM tumor. *Id.* TTFields interfere with GBM tumor cell division. *Id.* This action slows or stops GBM cells from dividing, and may destroy them. *Id.* Optune with temozalomide is indicated for the treatment of adult patients with *newly diagnosed* supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*See* https://www.optune.com/hcp/therapy/moa). *Id.* For treatment of patients who have *recurrent* GBM, Optune is indicated following histologically-confirmed or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. *Id.* The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. *Id.* Ms. Prosser is *newly diagnosed* with the disease. (Exh. 2, p. 1).

On April 8, 2011, Optune, previously called NovoTTF-100A System, received pre-market approval from the FDA for treatment of glioblastoma for use in patients with recurrent glioblastoma, based upon the result of a large randomized, controlled trial of patients with recurrent GBM.[1] (Exh. 5, pp. 32-36). The overall survival and progression-free survival to chemotherapy with minimal toxicity and an improvement in patients' quality of life, is demonstrated, compared to that of chemotherapy. *Id.* On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.[2] (Exh. 5, pp. 37-40).

The record includes National Comprehensive Cancer Network publications that provide clinical practice oncology guidelines from 2013 through 2018 for the management of both newly diagnosed and recurring central nervous system cancers.[3] (Exh. 5, pp. 14-29). Alternating electric field therapy was considered an effective treatment option for recurrent glioblastomas and oligodendrogliomas. (Exh. 5, p. 15). Along with (1) palliative support care, (2) systemic

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

[2] http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

[3] National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, *Central Nervous System Cancers*, version 1.2018.

chemotherapy, and (3) surgery or reirradiation, alternating electric field therapy is considered a fourth modality of cancer treatment. *Id.*

A 2012 article summarized results from a study comparing NovoTTF-100A (Optune) treatment to a physician's choice of chemotherapy treatment in recurrent glioblastoma cases.[4] (Exh. 5, pp. 1,803-1,813).

> This is the first controlled trial evaluating an entirely novel cancer treatment modality delivering electric fields rather than chemotherapy. No improvement in overall survival was demonstrated, however efficacy and activity with this chemotherapy-free treatment device appears comparable to chemotherapy regimens that are commonly used for recurrent glioblastoma. Toxicity and quality of life clearly favoured TTF.

(Exh. 5, p. 1,804).

Within three years, studies showed significant advancements. On December 15, 2015, the Journal of the American Medical Association (JAMA) published an article analyzing the results of a phase III clinical trial related to TTFT.[5] (Exh. 5, pp. 1,518-1,526). The analysis of the clinical trial with 315 participants showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival." (Exh. 5, p. 1,525). After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. (Exh. 5, p. 1,521).

On December 19, 2017, JAMA published an article that reports the findings of a phase III clinical trial involving 695 participants with glioblastoma.[6] (Exh. 5, pp. 1,529-1,550). The conclusion was:

> In the final analysis of this randomized clinical trial of patients with glioblastoma who had received standard radio-chemotherapy, the addition of TTFields [Optune] to maintenance temozolomide chemotherapy vs maintenance temozolomide alone, resulted in statistically significant improvement in progression-free survival and overall survival. These results are consistent with the previous interim analysis.

(Exh. 5, p. 1,549). The author noted that the findings were in contrast to the more than twenty-three randomized trials conducted during the previous decade that evaluated novel agents or

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[4] Stupp, Roger, M.D. et al., *NovoTTF-100A Versus Physician's Choice Chemotherapy In Recurrent Glioblastoma: A Randomized Phase III Trial Of A Novel Treatment Modality*, European Journal of Cancer, Volume 48, Issue 14, pp. 2192-2201 (September 2012).

[5] Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, JAMA (December 15, 2015).

[6] Stupp, Roger, M.D. et al., *Effect of Tumor-Treating Field Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma*, JAMA (December 19, 2017).

intensified treatment strategies for treatment of patients with newly diagnosed glioblastoma, and failed to demonstrate improved survival. (Exh. 5, pp. 1,548-1,549).

A 2018 article summarizes a study in which patients with newly diagnosed glioblastoma participated in a study conducted from July 2009 through November 2014, and were followed through December 2016.[7] (Exh. 5, pp. 1,551-1,559). Compared to patients in the temozolomide-alone part of the study, participants who received TTFields (Optune) had significantly longer deterioration-free survival in global health status, physical and emotional functioning, pain, and leg weakness. (Exh. 5, pp. 1,557-1,558).

The Medicare Administrative Contractor, initially and on redetermination, denied the claim for the services. The Qualified Independent Contractor (QIC) denied reconsideration of the claim on March 19, 2019. Both the Administrative Contractor and the QIC found that, based on the available documentation, Medicare requirements outlined in the LCD were not met. Ms. Prosser, filed a request for hearing before an Administrative Law Judge (ALJ) on March 27, 2019. (Exh. 3, pp. 1-3). Since the request was timely and the amount in controversy met the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 405.1002(a)(1), 405.1006(b)(1), this ALJ has jurisdiction to conduct the *de novo* review and issue a decision. 42 C.F.R. § 405.1000(d).

By Notice of Hearing served on April 4, 2019, the appeal was scheduled to be heard on May 29, 2019. As of the date of this decision, no contractor has responded to the Notice of Hearing.

An ALJ may decide a case on the record without hearing if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038(a). Inasmuch as this ALJ issues this decision as wholly favorable, no hearing will be held.

The issues before the ALJ include all the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in the Appellant's favor, for the claims or other appealed matters specified in the request for hearing. The issue was whether all Medicare coverage requirements have been met warranting payment for the Tumor Treatment Field Therapy.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health

[7] Taphoorn, Martin, MD et al., *Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma*, JAMA (February 1, 2018).

and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 405.1002. The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. 42 C.F.R. § 405.1014(c). The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term that is defined by the Social Security Act as including, among many other things, durable medical equipment. *See* Social Security Act § 1832(a)(1)(B); 42 C.F.R. §410.10(h). Notwithstanding any other provision of Title XVIII of the Social Security Act, no payment may be made under parts A or B for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A). Similarly, Medicare precludes payment to any claimant unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Social Security Act § 1833(e).

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:
    - o Scientific data or research studies published in peer-reviewed medical journals;
    - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
    - o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

> Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical

> community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

There is a Local Coverage Determination stating CMS' guidance for Tumor Treatment Field Therapy: CGS Administrators, LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy (TTFT) (January 2017). This LCD provides, without elucidation, that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.[8] The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (January 2017).

Analysis

The issue is whether the Tumor Treatment Field Therapy services are entitled to coverage. Pursuant to section 405.1032(a) of the regulations (42 C.F.R.), the unfavorable findings of the contractors are the issues before this ALJ. Both the Medicare Contractor and the QIC found, that based on the available documentation, Medicare requirements outlined in the LCD were not met. (Exh. 1, pp. 10, 31).

There is no NCD specific to TTFT. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

Ms. Prosser, in her prehearing brief, argues that the LCD L34823 does not apply to newly diagnosed glioblastoma cases. However, the LCD is silent on the type of glioblastoma and does not differentiate between newly diagnosed and recurrent glioblastoma. Consequently, LCD L34834 is applicable to this case, and I decline to follow it for multiple reasons. TTFT has been shown to be safe and effective for use in patients with recurrent and newly diagnosed glioblastoma, and it is medically reasonable and necessary to treat Ms. Prosser's condition.

LCD L34834 denies coverage for tumor treatment field therapy as not reasonable and necessary, omitting entirely the literature references in the prior LCDs. Data from the FDA, phase III clinical trials, and NCCN guidelines show the LCD, at best, is behind the medical literature curve – at least as applied to Ms. Prosser. The *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) provides more appropriate, relevant, and helpful guidance for making a determination as to whether an item or service is reasonable and necessary, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1.

[8] This latest version of the LCD, omits entirely the literature previously shown in the 2016 LCD (an update from the 2015 version, which is not markedly distinguishable).

Applying that guidance, this ALJ first finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. Premarket approval (PMA) entails the following:

> PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).[9]

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. The FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental. The FDA approval, along with the other evidence below, supports the conclusion that the device is safe, and not experimental or investigational.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. The results from these phase III trials also led to FDA approval for the Optune device. These trials showed that the Optune device was safe, non-investigational and effective. It is noteworthy that the 2015 study contains proof of efficacy. These trials show that the Optune device is appropriate for treatment of Ms. Prosser's glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

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[9]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm

Overall, a review of the literature available supports that the Optune device is safe and effective and not investigational/experimental. The use of the Optune device in populations with recurrent glioblastoma or newly diagnosed glioblastoma was proven effective and appropriate through phase III clinical trials. The use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT. (Exh. 5, pp. 692-1,421).

For the reasons stated above, Optune (TTFT) has been shown to be safe and effective, and is not experimental. Medicare coverage is thus available for the tumor treatment field therapy.

Conclusions of Law

Medicare coverage exists for the Optune Tumor Treatment Field Therapy services (E0766) provided to the Beneficiary for dates of service August 16, 2018, September 16, 2018, and October 16, 2018.

Order

The Medicare Contractor shall process the claim in accord with this decision.

IT IS SO ORDERED.

Dated: MAY 16 2019

Kimberley Woodyard
U.S. Administrative Law Judge